

ANCHORED FIDUCIAL APPARATUS AND METHODBackground of the Invention

This invention relates generally to an apparatus and method for locating a particular portion of an object that is not viewable and in particular to an apparatus and method for locating a portion of an object by placing a marker that is viewable at or near the portion of the object.

5 In many applications, it is not possible to directly view an object or a portion of an object that needs to be acted on in some manner. For example, to treat a target region, such as a lung tumor, with radiation, it is not possible to be able to view the actual tumor within the patient immediately before the radiation treatment. It is therefore necessary to have some mechanism for permitting the lung tumor to be located accurately so that the radiation treatment can be targeted 10 at the lung tumor while avoiding damage to healthy tissue.

In order to accurately track and target a target region, one or more fiducials may be used. Each fiducial is typically a substance that can be seen when an x-ray of the patient is viewed so that the lung tumor can be effectively located and targeted. Typically, the fiducials may be inserted into the patient during a simple operation. Each fiducial may be, for example, a radio-opaque substance that will be visible during an x-ray of the patient. These typical fiducials permit more accurate locating and targeting of the lung tumor, but there is a limit to the accuracy of targeting that can be achieved with these typical fiducials. In particular, the fiducials are normally placed into the lung tumor, but are not actually anchored to the lung tumor. Therefore, over time, the fiducials may move slightly or a large distance which makes the fiducials useless 20 to locate the lung tumor and requires that new fiducials be inserted into the patient. It may actually be worse if the fiducials only move a small distance since the surgeon may not realize that the fiducials have moved and continue the treatment with bad targeting information (from the misaligned fiducials) that may lead to the radiation being delivered to the wrong location. In fact, the radiation may be delivered less effectively (in a smaller amount) to the lung tumor 25 (which reduces the efficacy of the treatment) and delivered in a greater amount to the healthy

tissue surrounding the lung tumor which will damage the healthy tissue and cause undesirable side effects.

To solve this problem, it is desirable to provide fiducials that may be anchored into a target region so that the fiducials are not able to move away from the target region and/or 5 migrate. Thus, it is desirable to provide an anchored fiducial apparatus and it is to this end that the present invention is directed.

Summary of the Invention

The anchored fiducial apparatus and method in accordance with the invention overcomes the limitations of the prior art fiducials. In particular, the anchored fiducials may be placed into a 10 particular region to provide accurate location and tracking of that region. In one embodiment, the anchoring fiducial apparatus may be made of a radio opaque material that may be used to accurately locate a target region, such as a tumor, within a human patient during stereotaxic radiosurgery. The anchored fiducial apparatus in accordance with the invention anchors itself when it is placed into the region (of tissue) so that the anchored fiducial does not move/change 15 its location relative to the region over time. The anchored fiducial apparatus may be inserted into the region by various well known techniques wherein the anchored fiducial is in an unanchored position during insertion into the region. Once the fiducial apparatus is inserted into the region, it may be placed into an anchored position in a state which secures/anchors the fiducial apparatus 20 into the region (of tissue) and therefore unlikely to move and migrate over time as typical fiducials may.

The fiducial apparatus includes a body portion and one or more anchoring devices that anchor the fiducial apparatus into the region. In more detail, each anchoring device includes an elastic member and an anchor member. In two different embodiments, the anchor members have different shapes. In one embodiment, the anchor member is pyramidal shaped while in another 25 embodiment the anchor member is an elongated rectangularly shaped member.

Brief Description of the Drawings

Figure 1 is a diagram illustrating a first embodiment of the fiducial apparatus in accordance with the invention and a method for inserting the fiducial into a target region;

5 Figure 2a is a diagram illustrating the fiducial apparatus of Figure 1 in an unanchored position;

Figure 2b is a diagram illustrating the fiducial apparatus of Figure 1 in an anchored position;

10 Figure 3a illustrates an end view of the fiducial apparatus of Figure 1 when in the unanchored position;

Figure 3b illustrates an end view of the fiducial apparatus of Figure 1 when in the anchored position;

Figure 4 is a diagram illustrating a second embodiment of the fiducial apparatus in accordance with the invention and a method for inserting the fiducial into a target region;

15 Figure 5a illustrates the fiducial of Figure 4 in an unanchored position;

Figure 5b illustrates the fiducial of Figure 4 in an anchored position;

Figure 5c illustrates an end view of the fiducial of Figure 4 when in the anchored position;

20 Figure 5d illustrates another view of the fiducial of Figure 4 when in the anchored position;

Figure 6 is a diagram illustrating a third embodiment of the fiducial apparatus in accordance with the invention and a method for inserting the fiducial into a target region;

Figure 7a illustrates the fiducial of Figure 6 in an unanchored state;

Figures 7b and 7c illustrate the fiducial of Figure 6 in an anchored state;

Figure 8 illustrates another embodiment of the fiducial in accordance with the invention;

and

5 Figures 9A and 9B illustrate the fiducial of Figure 8 in an unanchored state and in an anchored state, respectively.

Detailed Description of a Preferred Embodiment

The invention is particularly applicable to a fiducial apparatus for locating a target region in a patient during surgery using electromagnetic radiation and it is in this context that the invention will be described. It will be appreciated, however, that the apparatus and method in accordance with the invention has greater utility since the described apparatus and method can be used to locate a portion of any object that is not readily viewable for a variety of different purposes. For example, the fiducial apparatus may be used for locating and targeting during other types of operations and medical procedures.

Figure 1 is a diagram illustrating a preferred embodiment of the fiducial apparatus 30 in accordance with the invention and a method for inserting the fiducial into a target region. In this embodiment, the fiducial apparatus 30 may be inserted into a patient using a specific insertion needle 32 (also known as a needle with stylet or an "introducer" that "extrudes" the fiducial). In particular, the target region within the patient is identified, the needle attached to a syringe is inserted into the target region and the fiducial apparatus 30 is expelled from the tip of the needle as is well known. The invention is not limited to the particular insertion method shown since the fiducial apparatus 30 may be inserted into the patient or any object by any other well known technique, such as by surgical implantation. In this embodiment, the fiducial apparatus may have a round cross-section (as shown in Figures 3a and 3b) since it must pass through the needle of the syringe. However, the invention is not limited to any particular size or shape of the fiducial apparatus as long as the fiducial apparatus is sufficiently large to be viewed on an x-ray or any

other similar imaging apparatus. In accordance with the invention, the fiducial apparatus may be made of any material which blocks the imaging energy so that the fiducial apparatus appears on an image generated by any typical imaging systems, such as x-rays. In a preferred embodiment, the fiducial apparatus may be made of a radio opaque material, such as gold. In other 5 embodiments, the fiducial may be made of a material so that it is viewable in a ultrasound image so that is may be used as a ultrasound fiducial. Now, more details of the fiducial apparatus in accordance with the invention will be described.

Figure 2a is a diagram illustrating the fiducial apparatus 30 of Figure 1 in an unanchored position, Figure 2b is a diagram illustrating the fiducial apparatus 30 of Figure 1 in an anchored position, Figure 3a illustrates an end view of the fiducial apparatus 30 of Figure 1 when in the unanchored position and Figure 3b illustrates an end view of the fiducial apparatus 30 of Figure 1 when in the anchored position. As shown in Figures 2a and 2b, the fiducial apparatus may include a body portion 34 and one or more anchoring devices 36 embedded into the body portion. In the preferred embodiment, the anchoring devices 36 are located on opposite sides of the body portion as shown in Figures 3a and 3b, but the invention is not limited to any particular orientation of the anchoring devices 36 relative to one another.

Each anchoring device 36, in this embodiment, may include a housing portion 38 that houses an elastic member 40, such as a spring, and an anchor member 42 attached to the elastic member 40. In this embodiment, the anchor member is a spike that anchors itself into the target tissue. The spike may be pyramidal shape. The other end of the elastic member is attached to the body portion so that the elastic member urges the anchor member 42 outwards away from the body portion. Thus, as shown in Figure 2b, once the fiducial apparatus exits the delivery mechanism, such as the needle of the syringe, so that the spring is no longer constrained, the anchor members 42 pop out from the body portion and embed themselves into the target region 20 so that the fiducial apparatus does not move/change position or migrate. Figure 2a and 3a illustrates the anchor members in a stored position while Figures 2b and 3b illustrate the anchor members in an anchoring state. Thus, the fiducial apparatus is anchored into its spot such that the accuracy of the location of the fiducial apparatus in the target region does not change over 25

time as happens with typical unanchored fiducial apparatus. Now, another embodiment of the fiducial apparatus in accordance with the invention will be described.

Figure 4 is a diagram illustrating a second embodiment of the fiducial apparatus 30 in accordance with the invention and a method for inserting the fiducial into a target region. In this embodiment, the fiducial apparatus 30 may be inserted into a patient using a needle 32. In particular, the target region within the patient is identified, the needle attached to a syringe is inserted into the target region and the fiducial apparatus 30 is expelled from the tip of the needle as is well known. The invention is not limited to the particular insertion method shown since the fiducial apparatus 30 may be inserted into the patient or any object by any other well known technique, such as by surgical implantation. In this embodiment, the fiducial apparatus may have a round cross-section (as shown in Figure 5c) since it must pass through the needle of the syringe. However, the invention is not limited to any particular size or shape of the fiducial apparatus as long as the fiducial apparatus is sufficiently large to be viewed on an x-ray or any other similar imaging apparatus. In accordance with the invention, the fiducial apparatus may be made of any material which blocks the imaging energy so that the fiducial apparatus appears on an image generated by any typical imaging systems, such as x-rays. In a preferred embodiment, the fiducial apparatus may be made of a radio opaque material, such as gold. In other embodiments, the fiducial may be made of a material so that it is viewable in a ultrasound image so that it may be used as a ultrasound fiducial. Now, more details of this embodiment of the fiducial apparatus in accordance with the invention will be described.

In particular, Figure 5a illustrates the fiducial 30 of Figure 4 in an unanchored position, Figure 5b illustrates the fiducial 30 of Figure 4 in an anchored position, Figure 5c illustrates an end view of the fiducial 30 of Figure 4 when in the anchored position and Figure 5d illustrates another view of the fiducial 30 of Figure 4 when in the anchored position. As shown in Figures 5a and 5b, the fiducial apparatus may include a body portion 34 and one or more anchoring devices 36 embedded into the body portion. In the preferred embodiment, the anchoring devices 36 are located on opposite sides of the body portion as shown in Figures 5c, but the invention is not limited to any particular orientation of the anchoring devices 36 relative to one another.

Each anchoring device 36, in this embodiment, may include a housing portion 50 (a trench in this embodiment) that houses an anchor member 52 and an elastic member 54, such as a spring, wherein the anchor member is attached to the elastic member. In this embodiment, the anchor member is an elongated rectangular shaped member anchored at one end so that as it is released from the housing portion, it anchors itself into the target region (See Figure 5b). The other end of the elastic member is attached to the body portion so that the elastic member urges the anchor member 42 outwards away from the body portion when the anchor member is released. Thus, as shown in Figure 5b, once the fiducial apparatus 30 exits the delivery mechanism, such as the needle of the syringe, so that the elastic member is no longer constrained, the anchor members 52 pop out from the body portion and embed themselves into the target region so that the fiducial apparatus does not move/change position or migrate. Figure 5a illustrates the anchor members in a stored position while Figures 5b – 5d illustrate the anchor members in an anchoring state. Thus, the fiducial apparatus is anchored into its spot such that the accuracy of the location of the fiducial apparatus in the target region does not change over time as happens with typical unanchored fiducial apparatus. Now, another embodiment of the fiducial apparatus will be described.

Figure 6 is a diagram illustrating a second embodiment of the fiducial apparatus 30 in accordance with the invention and a method for inserting the fiducial into a target region. In this embodiment, the fiducial apparatus 30 may be inserted into a patient using a needle and syringe 32. In particular, the target region within the patient is identified, the needle of the syringe is inserted into the target region and the fiducial apparatus 30 is expelled from the tip of the needle as is well known. The invention is not limited to the particular insertion method shown since the fiducial apparatus 30 may be inserted into the patient or any object by any other well known technique, such as by surgical implantation. In this embodiment, the fiducial apparatus may have a round cross-section (as shown in Figures 7b and 7c) since it must pass through the needle of the syringe. However, the invention is not limited to any particular size or shape of the fiducial apparatus as long as the fiducial apparatus is sufficiently large to be viewed on an x-ray or any other similar imaging apparatus. In accordance with the invention, the fiducial apparatus may be made of any material which blocks the imaging energy so that the fiducial apparatus appears on

an image generated by any typical imaging systems, such as x-rays. In a preferred embodiment, the fiducial apparatus may be made of a radio opaque material. In other embodiments, the fiducial may be made of a material so that it is viewable in a ultrasound image so that is may be used as a ultrasound fiducial. Now, more details of this embodiment of the fiducial apparatus in accordance with the invention will be described.

In particular, Figure 7a illustrates the fiducial 30 of Figure 6 in an unanchored state and Figures 7b and 7c illustrate the fiducial 30 of Figure 6 in an anchored state. In this embodiment, the fiducial apparatus is made out of a memory metallic substance, such as nitinol, which reacts to an electric field by bending as is well known. The fiducial apparatus may also be made of a material that is temperature sensitive and bends in response to a particular temperature range, such as the temperature within the human body. Thus, as shown in Figure 7a, an electric field is applied during the insertion of the fiducial apparatus so that the fiducial apparatus remains relatively straight. As shown in Figures 7b and 7c, once the adjacent electric field is removed and does not interact with the fiducial apparatus, the fiducial apparatus bends so that it is less likely to move within the target region.

Figure 8 illustrates another embodiment of the fiducial apparatus 30 in accordance with the invention and a method for inserting the fiducial into a target region. In this embodiment, the fiducial apparatus 30 may be inserted into a patient using a needle 32. In particular, the target region within the patient is identified, the needle is inserted into the target region and the fiducial apparatus 30 is expelled from the tip of the needle as is well known. The invention is not limited to the particular insertion method shown since the fiducial apparatus 30 may be inserted into the patient or any object by any other well known technique, such as by surgical implantation. In this embodiment, the fiducial apparatus may have a round cross-section since it must pass through the needle of the syringe. However, the invention is not limited to any particular size or shape of the fiducial apparatus as long as the fiducial apparatus is sufficiently large to be viewed on an x-ray or any other similar imaging apparatus. In accordance with the invention, the fiducial apparatus may be made of any material which blocks the imaging energy so that the fiducial apparatus appears on an image generated by any typical imaging systems, such as x-rays. In a preferred

embodiment, the fiducial apparatus may be made of a radio opaque material. In other embodiments, the fiducial may be made of a material so that it is viewable in a ultrasound image so that it may be used as a ultrasound fiducial. Now, more details of this embodiment of the fiducial apparatus in accordance with the invention will be described.

5 Figures 9A and 9B illustrate the fiducial of Figure 8 in an unanchored state and in an anchored state, respectively. In this embodiment, the fiducial apparatus may include an elastic body portion that may be stretched by the insertion of a fluid or other material into the body portion. As shown in Figure 9A, when the fiducial apparatus is in the unanchored state, the body portion is empty. To put the fiducial apparatus into the anchored state, a fluid or other material
10 60 is inserted into the body portion 58 that expands as shown to anchor the fiducial into the target region. As with the other embodiments, the fluid may be radio opaque material or a ultrasound opaque material.

15 While the foregoing has been with reference to a particular embodiment of the invention, it will be appreciated by those skilled in the art that changes in this embodiment may be made without departing from the principles and spirit of the invention, the scope of which is defined by the appended claims.